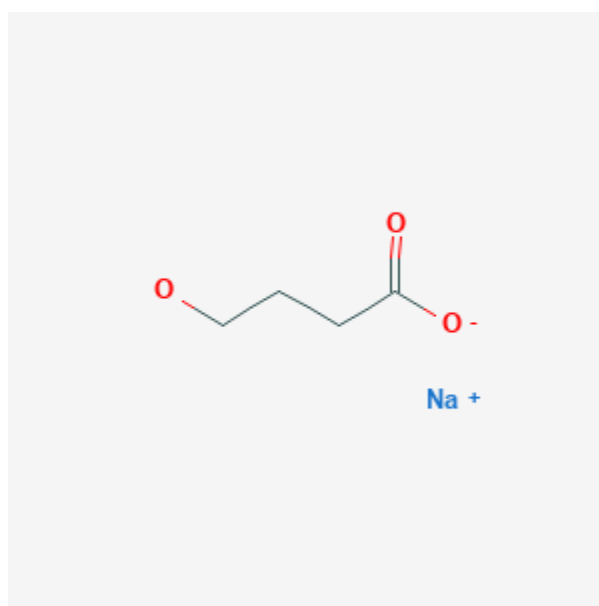


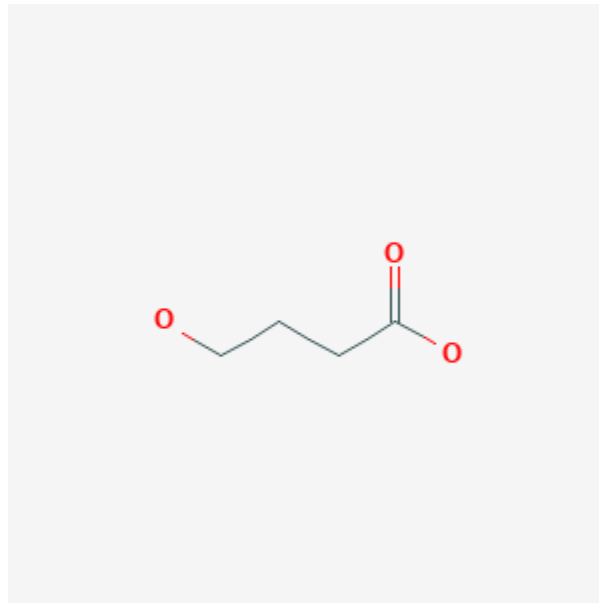


Sodium Oxybate

Revised: December 3, 2018.

CASRN: 502-85-2 591-81-1





Drug Levels and Effects

Summary of Use during Lactation

Sodium oxybate is the sodium salt of gamma-hydroxybutyric acid (GHB). GHB is an endogenous substance and low amounts are normally found in breastmilk. Large doses of GHB have been used as a substance of abuse. Infants have been successfully breastfed by mothers taking sodium oxybate therapeutically for narcolepsy. With the typical 2 doses per night treatment regimen, nursing should usually be withheld from the time of the first dose to 4 to 6 hours after the second dose and breastfeeding can be continued during the day.[1] No information is available on the use or safety of GHB as a drug of abuse during breastfeeding.

Drug Levels

Maternal Levels. Blood and breastmilk samples were collected from 20 nursing mothers twice between the second week and fourth month postpartum. Endogenous breastmilk levels averaged 0.35 and 0.36 mg/L at the two time points. The authors proposed establishment of a normal GHB breastmilk reference range of 0.13 to 1.03 mg/L.[2]

A woman with narcolepsy with cataplexy took a single dose of sodium oxybate 4.5 grams. Breastmilk samples were obtained separately from the right and left breasts at 7 and 9 weeks postpartum. Milk concentrations from the right breast at week 9 postpartum had a peak value of 23.2 mg/L at 1 hour after the dose, decreasing to 3.1 mg/L at 4 hours after the dose and 1 mg/L at 5 hours after the dose, at which time the concentration was within the proposed endogenous breastmilk reference range of 0.13 to 1.03 mg/L. No differences were found between left and right breast or between week 7 and 9 samples.[2]

A paper reported two mothers with narcolepsy and cataplexy who collected breastmilk samples during therapeutic use of sodium oxybate. Neither breastfed her infant during this time. One mother who was 5 months postpartum took 3 grams of sodium oxybate twice a night for one night and 4.5 grams twice a night for a second night. Pre-dose breastmilk levels were 0.66 and 0.6 mg/L (6.3 and 5.8 micromoles/L) on the two nights, which represent normal endogenous milk levels. At 4 hour after the first 3 gram dose, the breastmilk level was 1.09 mg/L (10.44 micromoles/L); the milk level at 3 to 4 hours after the second dose was 1.7 mg/L (16.5 micromoles/L). At 4 hour after the first 4.5 gram dose, the breastmilk level was 2.5 mg/L (23.58 micromoles/L); the milk level at 3 to 4 hours after the second dose was and 2.9 mg/L (27.5 micromoles/L). Breastmilk levels had returned to normal physiologic levels by 6 to 7 hours after the second doses. The second mother collected milk

samples after two pregnancies. Because of inconsistent results and a lack of baseline values with the first pregnancy, only results from the second pregnancy are reported here. At 9 months postpartum, she collected milk samples on 2 days while taking 2.25 and on one day while taking 3 grams twice nightly. A pre-dose sample contained 0.8 mcg/L (7.6 micromoles/L). Breastmilk oxybate concentrations were 1.5 and 3 mg/L (14.6 and 29.2 micromoles/L) at 4 hours after the second dose of 2.25 grams twice nightly. At 10 and 16 hours after her second dose, breastmilk levels were at baseline values of 1.6 and 1.2 mg/L (15.41 and 11.22 micromoles/L). Following twice nightly doses of 3 grams, her breastmilk levels at 4, 10 and 16 hours after the second dose were 3.5, 0.9 and 0.8 mg/L (34.01, 9.52 and 8.11 micromoles/L), respectively. The authors concluded that waiting 6 hours after the second dose before resuming breastfeeding would be preferred.[3] Some of the technical aspects of study have been questioned.[4]

Infant Levels. Relevant published information was not found as of the revision date.

Effects in Breastfed Infants

A woman was taking 4.5 grams of sodium oxybate twice daily (exact times not reported) for narcolepsy and cataplexy throughout pregnancy and lactation. She breastfed her infant (extent and times not stated). No adverse infant effects were reported.[2]

A woman with narcolepsy took sodium oxybate 4 grams each night at 10 pm and 2 am as well as fluoxetine 20 mg and cetirizine 5 mg daily throughout pregnancy and postpartum. She breastfed her infant except for 4 hours after the 10 pm oxybate dose and 4 hours after the 2 am dose. She either pumped breastmilk or breastfed her infant just before each dose of oxybate. The infant was exclusively breastfed or breastmilk fed for 6 months when solids were introduced. The infant was evaluated at 2, 4 and 6 months with the Ages and Stages Questionnaires, which were within the normal range as were the infant's growth and pediatrician's clinical impressions regarding the infant's growth and development.[5]

Effects on Lactation and Breastmilk

Relevant published information was not found as of the revision date.

Alternate Drugs to Consider

Amphetamine, Methylphenidate

References

1. Swick TJ. Postnatal treatment of women with narcolepsy who choose to breastfeed-time for a reappraisal? *Sleep Med.* 2017;36:178-9. PubMed PMID: 28684017.
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4. Busardo FP, Pichini S. GHB concentration in breast milk of narcoleptic women treated with sodium oxybate. How important it is to be careful when interpreting values. *Sleep Med.* 2017;40:129. PubMed PMID: 28821387.
5. Gashlin LZ, Sullo D, Lawrence RA et al. Treatment of narcolepsy with sodium oxybate while breastfeeding: A case report. *Breastfeed Med.* 2016;11:261-3. PubMed PMID: 27057786.

Substance Identification

Substance Name

Sodium Oxybate

CAS Registry Number

502-85-2 591-81-1

Drug Class

Breast Feeding

Lactation

Anesthetics

Hypnotics and Sedatives

GABA Modulators